analgesic with a sustained action (element B). --

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A method of alleviating pain in a patient in need thereof comprising

administering to said patient a preparation according to any one of claims 1-11. --

CONDITIONAL PETITION FOR EXTENSION OF TIME

If entry and consideration of the amendments above requires an extension of time, Applicants respectfully request that this be considered a petition therefor. The Commissioner is authorized to charge any fee(s) due in this connection to Deposit Account No. 14-1263.

ADDITIONAL FEE

Please charge any insufficiency of fees, or credit any excess, to Deposit Account No. 14-1263.

REMARKS

Applicants respectfully request reconsideration and allowance of this application in view of the amendments above and the following comments.

A number of new claims have been added, but no new matter has been introduced. Claims 5-8 are supported by page 3, lines 27-30. Claim 9 is supported by, for example, both

examples, which have the element A in the outer coating and the element B in the inner core tablet. Claim 10 is supported by page 2. Claim 11 is supported by page 3, lines 12-15. New claim 12 has clear support throughout the entire disclosure. No new matter has been added.

The sole issue for consideration is the rejection of claims 1-4 under 35 USC § 103(a) as being obvious over Griffin, U.S. Patent No. 5,702,723. In response, Applicants respectfully request that the Examiner reconsider and withdraw this rejection.

According to the Examiner, Griffin discloses a single pill for oral administration, wherein the outer layer comprises an active substance that will dissolve and have a beneficial local effect somewhere in the mouth or upper respiratory layer, and an inner layer comprising an active substance that will dissolve in the gastrointestinal area and have a beneficial systemic effect. The Examiner points out that Griffin sets forth several examples, one of which contains a pain reliever in an outer layer and an antihistamine in an inner layer. In response, Applicants emphasize that the present claims require the presence of both a locally acting analgesic and a systemically acting analgesic. Thus, Griffin's combination of a pain reliever in an outer layer and an antihistamine in an inner layer is fundamentally quite different from what is presently claimed. Thus, Griffin distinguishes been pain relievers, on the one hand, and antihistamines, on the other hand. See, Griffin at column 4, lines 37-38 ("pain reliever or antihistamine.")

Possibly, the closest Griffin comes to the present invention is the embodiment at column 4, lines 37-40, of a treatment for a sore throat in the outer coating, and a pain reliever or antihistamine or traditional cold ingredients in an inner portion of the tablet. At column 4, lines 32-35, in connection with a different embodiment, Griffin suggests that a pain reliever in the outer coating could be used to treat "any painful throat conditions accompanying the cold."

However, in connection with the embodiment at column 4, lines 37-40, Griffin makes a distinction between "a treatment for sore throat," on the one hand, and "a pain reliever," on the other hand. Accordingly, even in this embodiment, there is no clear suggestion to use both a locally acting analgesic and a systemically acting analgesic, as presently claimed.

In point of fact, there is nothing in Griffin that would have motivated persons skilled in the art to make the present preparations containing both a locally acting *analgesic* and a systemically acting *analgesic*. Although the Examiner appears to take the positions that the disclosures of Griffin encompass the present invention, and, if the correct selections were made among the possibilities disclosed therein, then the present invention would be achieved, the fact remains that there is nothing in Griffin to highlight the selections needed to achieve the present preparations, and, thus, nothing to have motivated persons skilled in the art to make the present preparations. Further on this point, Applicants would call the attention of the Examiner to the decision in *In re Baird*, 29 USPQ2d 1550 (Fed. Cir. 1994). In that case, the Court expressly held that "[t]he fact that a claimed compound may be encompassed by a disclosed generic formula

does not by itself render that compound obvious." See, Baird, 29 USPQ2d at 1552. While it is true, and this was accepted by the Court in Baird, that a reference must be considered not only for what it expressly teaches, but also for what it fairly suggests, the Examiner has not explained why, given the breadth of the reference teachings, and the lack therein of any subgeneric language or examples leading towards the inventive preparations, a person of ordinary skill in the art would have been motivated to make and use the instant preparations as claimed. Applicants submit that a person having ordinary skill in the art, given Griffin, would not have been motivated to make and use the instant preparations as claimed. Consequently, Applicants respectfully request that the Examiner reconsider and withdraw this rejection althogether.

Applicants also emphasize that claims 6-11 should be nonobvious over Griffin, as the limitations of these claims are nowhere taught or suggested by Griffin.

Applicants believe that the foregoing constitutes a bona fide response to all outstanding objections and rejections.

Applicants also believe that this application is in condition for immediate allowance. However, should any issue(s) of a minor nature remain, the Examiner is respectfully requested to telephone the undersigned at telephone number (212) 808-0700 so that the issue(s) might be promptly resolved.

Early and favorable action is earnestly solicited.

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Respectfully submitted,

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CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that the foregoing Amendment under 37 CFR § 1.11 and the accompanying Petition for Extension of Time (10 pages total) are being facsimile transmitted to the United States Patent and Trademark Office on the date below:

Date: September 21, 2001

Kurt G. Briscoe